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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,288	04/16/2004	Janusz Marcinkiewicz	JMA01	4290

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EXAMINER

ISSAC, ROY P

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/825,288

Applicant(s)

MARCINKIEWICZ ET AL.

Examiner

Roy P. Issac

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/16/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Status of the application

Acknowledgment is made of applicant's claim for foreign priority to under POLAND P - 359792 filed on 04/22/2003 and POLAND P - 367052 filed on 04/07/2004 under 35 U.S.C. 119(a)-(d). The certified copy of the priority of POLAND P - 359792 and POLAND P - 367052 and the English translations have been filed 06/07/2004 in the instant application.

Claims 1-19 are currently pending, and are examined on the merits herein.

Claim Objections

Claims 11, 14 and 18 are objected to because of the following informalities: Claims recite the term "cetomakrogel". This word should be spelled "cetomacrogol." Appropriate correction is required.

Claim 19 is objected to because of the following informalities: Claim 19 recites, "contains further a lipophyllic phase – liquid paraffin, acetyl alcohol and an (sic) hydrophyllic phase – propylene glycol and estolate". The recitation does not indicate whether the claim is open to other compounds or compositions that can be considered either hydrophilic or lipophilic. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of acne and for microbicidal activity against *Propionibacterium acnes* and *Staphylococcus epidermides*, does not reasonably provide enablement for all pathogenic bacteria and fungi. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to inhibiting pathogenic bacteria and fungal growth using taurine bromamine.

The state of the prior art

Bacteria and fungi are known for skin infections. (Skin and wound infections; and overview, American Family Physician, 57, 1998, 2424-2432; PTO-892, Cited by the examiner). Staphylococci is known to cause impetigo, eczthyma and folliculitis. On the other hand fungi cause many different types of skin infections broadly referred to as dermatomycoses. The systematic treatment of staphylococci infection includes treatment with beta-lactam-resistant antibiotics. Topical mupirocin and erythromycin are often used. (American Family Physician; Section titled "Impetigo"). In case of infection caused by Pseudomonas, ciprofloxacin is often used. (American Family Physician; Section titled "Folliculitis and Related Conditions", Paragraph 2).

The diagnosis of fungal infections is primarily based on the presenting pattern rather than culture or other test results. (American Family Physician; Section titled "Fungal and Yeast Infections"). For the fungal infection of scalp, griseofulvin, terbinafine and itraconazole are used. (American Family Physician; Section titled "Dermatophytosis", paragraph 4).

Different types of bacteria cause a variety of diseases and based on the type of bacterial infection different types of drugs are used. Fungal infections also require diagnosis that is different from bacterial infections and the use of anti-fungal agents that are different from anti-bacterial agents.

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The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The claims are broad since they encompass treating all fungal and bacterial growth or infection.

The amount of direction or guidance presented: Applicant provides directions for the use of taurine bromamine against acne as well as two bacterial species. However directions do not show how it can be used to inhibit fungal growth. No evidence of its usefulness against fungal growth is provided.

The predictability or unpredictability: The effectiveness of taurine bromamine against two bacterial species does not provide any indications as to its effectiveness against fungi growth. The effectiveness against two species of bacteria does not provide adequate guidance for its effectiveness against other classes of bacteria.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of*

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California v. Eli Lilly and Co. Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the pharmaceutical compositions herein.

The presence or absence of working examples and the quantity of experimentation necessary:

Applicant provides examples of taurine bromamine's effectiveness against two bacterial species. There are no examples of said comound's use against fungi.

Thus, the evidence in the examples is also not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition.

Note that the court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operabilityof any other species." (emphasis added, see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). In the instant application, it is not clear what dosage levels will be effective against other types of bacteria and whether most other bacterial growth can be inhibited by said compound.

Thus, the specification fails to provide clear and convincing evidence in sufficient support of the broad use of taurine bromamine having those functions

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recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search and undue experimentation for the embodiments of any known and unknown compounds having those functions encompassed in the instant claims suitable to practice the claimed invention.

Genentech, 108 F.3d at 1366, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test taurine bromamine against all bacteria and fungi encompassed in the instant claims with no assurance of success.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of the term “estolate” renders the claim indefinite.

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Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7-9 recites "a solution in an ethyl-cellulose gel", "a solution in a cream", and "a solution in a powder", respectively. It is not clear how a taurine bromamine can act as a solution in the other forms of phases described. As such, said recitations renders the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yazdanbakhsh et. al. (PTO-892; Cited by the examiner).

Yazdanbakhsh et. al. discloses the use of taurine bromamine as an agent against the parasitic worm *Schistosomula mansoni* and *S. haematobium*. (Abstract and Page 106, Column 1, lines 1-5). Yazdanbakhsh et. al. further discloses the use of 10 μ M and 100 μ M taurine chloramines and taurine bromamine. (Page 107, Column 2, Figure 1). Yazdanbakhsh et. al discloses the use of taurine bromamine in Dulbecco's MEM buffer, a buffer in the physiological pH range.

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The recitations, "microbicidal composition", "main ingredient of soap used for disinfecting a human skin", "used as a medicine in treatment of pathological dermal conditions, especially in treatment of acne", "is used as a cosmetic in treatment of pathological dermal conditions, especially in treatment of acne" are considered recitation of intended use of taurine bromaine. Note that it is well settled that "intended use" of a composition or product, will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount, as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Thus, claims 3-6 and 8-9 are anticipated by Yazdanbakhsh et. al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagl et. al. (PTO-892; Cited by the examiner) in view of Yazdanbakhsh et. al. (PTO-892; Cited by the examiner).

Nagl et. al. teaches that taurine chloramine (also known as N-Chlorotaurine) has bactericidal properties. (Page 2507, Abstract). Nagl. et. al. further teaches that taurine chloramines has bactericidal property against a variety of different bacterial organisms, in particular *staphylococcus aureus* and *staphylococcus epidermidis*. (Page 2509, Table 1). Nagl et. al. further teaches that taurine chloramine has bactericidal and fungicidal activity in concentration ranges of 0.55 to 55mM. (Page 2507, Column 1, Paragraph 4 to Column2, Paragraph 1).

Nagl et. al. does not expressly disclose the bactericidal or fungicidal activity of taurine bromamine.

The disclosure of Yazdanbakhsh et. al. is dicussed above in the 102 rejection.

It would have been obvious to one of ordinary skill in the art at the time invention was made to use taurine bromamine as an antibacterial or antifungal agent because Nagl et. al. teaches that taurine chloramine is an effective antifungal and antibacterial agent and Yazdanbakhsh et. al. teaches the use of taurine bromamine which has very similar structure to taurine chloramine. The only difference between the structures of these compounds is the substitution of one halogen, bromine for another halogen, chlorine.

One of ordinary skill in the art would have been motivated to use taurine bromamine because taurine bromamine is structurally very similar to taurine bromamine. If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan

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of ordinary skill to make the claimed species. It is a reasonable expectation that similar species usually have similar properties. See *Dillon*, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also, *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214. In fact, similar properties may formally be presumed when compounds are very close in structure. *Dillon* 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904, as noted in MPEP 2144.

Thus, claims 1-2 are obvious over the combined teachings of the prior art.

Claims 7 and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Nagl et. al.* (PTO-892; Cited by the examiner) in view of *Yazdanbakhsh et. al.* (PTO-892; Cited by the examiner), further in view of *Patel et. al.* (U.S. Patent No. 6,750,224).

The disclosure of *Nagl et. al.* is discussed above.

Nagl et. al. does not expressly disclose the bactericidal or fungicidal activity of taurine bromamine or the use of taurine bromamine with other cosmetic agents, in particular cetomacrogol or talc or liquid paraffin or propylene glycol or cellulose or glycerol.

The disclosure of *Yazdanbakhsh et. al.* is discussed above.

Patel et. al. discloses the use of methyl cellulose, glycerol (Column 22, lines 15-25), talc (Column 22, lines 45-52), cetamacrogol, liquid paraffin, purified water and propylene glycol (Column 41, Composition example 4) with antimicrobial agents. *Patel et. al.* further discloses that the resistance to drugs by

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staphylococcus aureus and *staphylococcus epidermidis* are of grave concern.

(Column 1, lines 39-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use taurine bromamine in combination with the commonly used pharmaceutical and cosmetic ingredients of claims 7 and 10-19 because a structurally similar compound, taurine chloramine, was found effective as an antibacterial agent and the '224 patent discloses the use of said ingredients in antibacterial compositions.

One of ordinary skill in the art would have been motivated to use taurine bromamine in combination with said ingredients because a structurally similar compound was found to be effective against *staphylococcus aureus* and *staphylococcus epidermidis* bacteria and the "224 patent discloses the problems of drug resistance against said bacteria. As discussed above, it would have been obvious to a person of ordinary skill in the art to use a structurally similar compound for the same purpose.

Thus, claims 7 and 10-19 are obvious over the combined teachings of the prior art.

No claims are allowed.

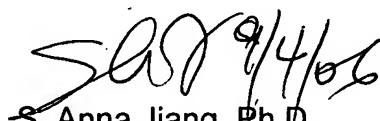
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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